JUN 1 1 2001

K 010634

510(k) Summary for Heartstream XL and XLT Defibrillator/Monitors Including Synchronized Cardioversion of Atrial Fibrillation

Date Summary Prepared

March 1, 2001

Submitter's Name and Address

Agilent Technologies
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3000 Minuteman Road
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Contact Person

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Device Name

Proprietary Name:	Heartstream XL and XLT Defibrillator/Monitor
Common Name:	Defibrillator/Monitor
Classification Names:	Low-Energy Defibrillator, Defibrillator Automatic External

Predicate Devices

The legally marketed devices to which Agilent Technologies claims equivalence for the Heartstream XL and XLT Defibrillator/Monitor are as follows:

- Hewlett-Packard, CodeMaster, M1722B Defibrillator/Monitor

The design of the Heartstream XL and XLT Defibrillator/Monitor is substantially equivalent in safety and efficacy to the device listed above for synchronized cardioversion of atrial fibrillation.

Device Description

The Heartstream XL and XLT Defibrillator/Monitor has two modes of operation: AED and manual. In manual mode, the Heartstream XL is a fully-featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS) procedures. Manual operation allows users to select energy levels for external and internal defibrillation, deliver synchronized shocks, and perform non-invasive external pacing.

The Heartstream XL and XLT defibrillator uses the Heartstream SMART Biphasic waveform for defibrillation.

Intended Use

The Heartstream XL and XLT Defibrillator/Monitor is a fully featured, external defibrillator intended for use by qualified medical personnel, trained in either Advanced Cardiac Life Support or Basic Life Support, in a hospital or pre-hospital environment.

Comparison of Technology Characteristics

The Heartstream XL and XLT Defibrillator/Monitor employs similar technologies as the predicate device used for comparison.

Clinical Tests Used in Determination of Substantial Equivalence

The objective of the testing performed on the Defibrillator/Monitor was to determine whether the device's revised function raise any questions regarding the safety or efficacy of the device. The philosophy of this approach is to show a comparison of monophasic waveform to SMART biphasic waveform in synchronized cardioversion of AF. It can then be concluded that there are no questions with respect to safety or effectiveness of the new indications for the Heartstream XL and XLT.

Conclusion from Testing

Based on the results of the clinical testing described above, it is concluded that the new indication for the Heartstream XL and XLT do not raise any questions regarding the safety or efficacy as compared with the predicate device. It is considered to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1 2001

Mr. Richard J. Peterson
Agilent Technologies, Inc.
3000 Minuteman Road
Andover , MA 01810-1099

Re: K010634
Trade Name: Heartstream XL and XLT Defibrillator/Monitor
Regulatory Class: III (three)
Product Code: MKJ
Dated: March 1, 2001
Received: March 2, 2001

Dear Mr. Petersen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010634

Device Name: Agilent Technologies, Heartstream XL and XLT Defibrillator/Monitors

Indications For Use: Synchronous defibrillation is indicated for termination of atrial fibrillation. The SMART Biphasic waveform utilized in the Heartstream XL and XLT Defibrillator/Monitor has undergone clinical testing demonstrating its safety and effectiveness for cardioversion of atrial fibrillation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010634